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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/750,921

12/31/2003

Rance A. Winkler

14.008011 CON

1909

38732 7590 01/23/2009

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EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/750,921	<b>Applicant(s)</b> WINKLER, RANCE A.	
	<b>Examiner</b> John P. Lacyk	<b>Art Unit</b> 3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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Claims 12-21 and 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/29/08.

Newly amended claims 22-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 22 has been amended to generally add the limitations of claims 19-20 which were previously withdrawn as being drawn to a nonelected invention (see above). Therefore since claim 22 and corresponding dependent claims are now directed to a nonelected invention these claims have also been withdrawn.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al (5,913,813).

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Williams et al discloses a catheter for treatment of proliferative tissue using brachytherapy. Williams et al discloses a spacing element or apparatus (36) in the form of an expandable balloon, which is "integrally formed" with the insertion member (12) and positions the brachytherapy device at a distance apart from the surrounding tissue, equal to the height of the balloon. The spacing element is movable between a deflated closed position and an inflated open position. Williams et al further teaches that the spacing element forms a radio-opaque barrier between the brachytherapy device and the surrounding tissue when expanded (column 2, lines 49-50).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al in view of Applicant's specification.

Williams et al discloses the claimed device except for the spacing element being disk-shaped in the open position. The courts have shown (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)) that without a showing of criticality a change in shape is considered to have been an obvious expedient depending on its suitability for the intended use of the device. Therefore to make the spacing element any desired shape depending on its suitability for the intended use would have been obvious to one skilled

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in the art. Further, as pointed out in applicant's specification (page 10, lines 6-7) one of ordinary skill in the art would know that the spacing element could be any shape.

Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al in view of Flexmedics Brochure.

Williams et al discloses the claimed device except for specifically using a shape memory material. The Flexmedics Brochure teaches that it is well known to use a shape memory material with many different medical devices including catheters.

Therefore a modification of Williams et al such that the spacing element or balloon catheter is made from a shape memory material would have been obvious to one skilled in the art in view of the teachings of Flexmedics which shows that such a material is well known in the art. Further one would have been motivated to modify the Williams et al device since this would be the mere substitution of one known way to inflate the balloon for another and allow the balloon to inflate without the need for using a fluid to inflate.

Applicant's arguments filed 10/16/08 have been fully considered but they are not persuasive. Applicant argues that Williams fails to teach that the spacing distance of the spacing element is equal to its height, but rather the difference in circumferences between the inner chamber 30 and the balloon 36. The examiner's position is that the said difference between the inner chamber 30 and the balloon 36 is considered to be the "height" of the spacing element. As can be seen in Figures 1 and 3, the brachytherapy device is disposed within a surgical extraction site and is at a distance

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apart from the tissue surrounding the surgical extraction site the distance that the device is spaced is the amount the balloon 36 is inflated to, therefore that distance is considered to be the "height" of the spacing element. Even though the spacing element goes all the way around the inner chamber 30, the "height" is only the distance between the chamber and the tissue.

Applicant argues, with respect to claims 6 and 8 that Applicant's specification is not prior art and that Applicant's recitation of equivalents is not a statement that they are obvious. As noted in the rejection the courts have shown that such a change in shape is considered an obvious expedient, Applicant's specification was merely used to show that the shape of the spacing element is not a critical feature of the device and therefore a modification of the shape would have been obvious to one skilled in the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/  
Primary Examiner, Art Unit 3735